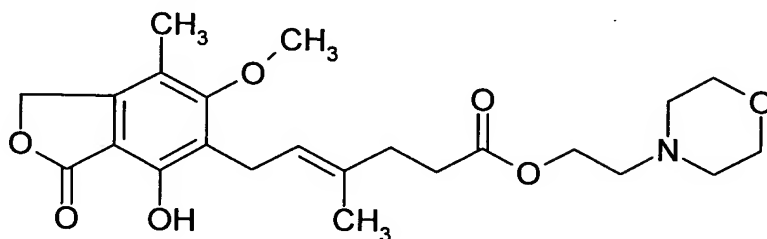


What is claimed is:

1. Process for the production of mycophenolate mofetil [mycophenolic acid 2-(4-morpholinyl)ethyl ester] of formula



whereby a reactive derivative of mycophenolic acid is produced in an inert solvent and is reacted with 4-(2-hydroxyethyl)morpholine, and the resulting mycophenolate mofetil is isolated from the reaction mixture, characterised in that

- I) 4-(2-hydroxyethyl)morpholine is added under controlled conditions to the solution of the reactive derivative of mycophenolic acid, whereby the reaction takes place under acidic reaction conditions, and
II) isolation of mycophenolate mofetil is effected by forming an acid addition salt and subsequently releasing the free base.

2. Process according to claim 1, characterised in that 4-(2-hydroxyethyl)morpholine is added to the solution of the reactive derivative of mycophenolic acid.

3. Process according to claim 1 or 2, characterised in that it contains the following process steps:

- a) activation of mycophenolic acid by forming a reactive derivative
b) reacting the reactive derivative of mycophenolic acid with 4-(2-hydroxyethyl)morpholine by esterifying to mycophenolate mofetil under acidic reaction conditions,
c) isolating mycophenolate mofetil through the formation of an acid addition salt, and
d) releasing the free base of mycophenolate mofetil from the acid addition salt.

4. Process according to one of claims 1 to 3, characterised in that the reactive derivative of mycophenolic acid is an activated carboxylic acid derivative.

5. Process according to one of claims 1 to 4, characterised in that the activated carboxylic acid derivative of mycophenolic acid is an acid halide.
6. Process according to one of claims 1 to 5, characterised in that the acid halide is an acid chloride.
7. Process according to one of claims 1 to 6, characterised in that activation of mycophenolic acid (process step a) is effected according to Vilsmeier technology.
8. Process according to claim 7, characterised in that the Vilsmeier reagent employed is the combination of N,N-dimethylformamide and oxalyl chloride.
9. Process according to one of claims 1 to 8, characterised in that the inert solvent, in which the activation reaction (process step a) and the esterification reaction (process step b) is carried out, is an acetic acid (C₁-C₄) alkyl ester or a halogenated hydrocarbon, optionally in the presence of a cosolvent.
10. Process according to claim 9, characterised in that the inert solvent is ethyl acetate or dichloromethane, optionally in the presence of a cosolvent.
11. Process according to claim 9 or 10, characterised in that the cosolvent is an organic amide.
12. Process according to one of claims 1 to 11, characterised in that the acid addition salt of mycophenolate mofetil is the oxalate or the hydrochloride of mycophenolate mofetil.
13. Process according to one of claims 1 to 12, characterised in that the formation of mycophenolate mofetil oxalate is effected from ethyl acetate or dichloromethane, optionally in the presence of a cosolvent from the group of ketones, (C₁-C₄)-alcohols or mixtures of the two.
14. Process according to one of claims 1 to 12, characterised in that the formation of mycophenolate mofetil hydrochloride is effected in ethyl acetate, optionally in the presence of an organic amide.

15. Use of mycophenolate mofetil oxalate as an intermediate in the production of mycophenolate mofetil or its pharmaceutically acceptable salts by the process according to one of claims 1 to 14.
- 5 16. Mycophenolate mofetil oxalate in crystalline form and its hydrates and solvates.